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ENCASED IMPLANT AND METHODS

Technical Field

This disclosure relates to vascular implants, methods of making, and methods of using.

Background

U.S. Patent No. 5,944,019, issued August 31, 1999, teaches an implant for defining a blood flow conduit directly from a chamber of the heart to a lumen of a coronary vessel. An embodiment disclosed in this patent teaches an L-shaped implant in the form of a rigid conduit having one leg sized to be received within a lumen of a coronary artery and a second leg sized to pass through the myocardium and extend into the left ventricle of the heart. As disclosed in the '019 patent, the conduit is rigid and remains open for blood flow to pass through the conduit during both systole and diastole. The conduit penetrates into the left ventricle in order to prevent tissue growth and occlusions over an opening of the conduit. U.S. Patent No. 5,944,019 is incorporated by reference herein.

U.S. Patent No. 5,984,956, issued November 16, 1999, discloses an implant with an enhanced fixation structure. The enhanced fixation structure includes a fabric surrounding at least a portion of the conduit to facilitate tissue growth on the exterior of the implant. U.S. Patent No. 5,984,956 is incorporated herein by reference. U.S. Patent No. 6,029,672 issued February 29, 2000 teaches procedures and tools for placing a conduit. U.S. Patent 6,029,672 is incorporated herein by reference.

Improvements in implants continue to be desirable.

Summary

In one aspect, a vascular implant is provided that includes a scaffold and a tubing in covering relation to the scaffold. Preferably, the scaffold completely embeds the scaffold.

In another aspect, a method of making a vascular implant is provided. The method includes completely covering a scaffold interior surface and exterior surface with a tubing.

In another aspect, a method for performing a coronary vessel bypass procedure is provided. The method includes forming a blood flow path from a heart chamber directly to a coronary vessel by placing a conduit in a heart wall between the chamber and the vessel. The conduit includes tubing completely lining both an interior surface of the conduit and an exterior surface of the conduit.

Brief Description of the Drawings

FIG. 1 is a side sectional view of one embodiment of an implant shown in place in a human heart wall with the implant establishing a direct blood flow path from a heart chamber to a coronary vessel, constructed according to principles of this disclosure;

FIG. 2 is a cross-sectional view of the embodiment of the implant shown in FIG. 1 in one step of constructing the implant;

FIG. 3 is a cross-sectional view of the implant shown in FIG. 2 during another step of making the implant;

FIG. 4 is a cross-sectional view of the implant shown in FIGS. 2 and 3 in another step of making the implant;

FIG. 5 is a side sectional view of a second embodiment of an implant shown in place in a human blood vessel, constructed according to principles of this disclosure;

FIG. 6 is a cross-sectional view of the embodiment of the implant shown in FIG. 5 during one step of constructing the implant;

FIG. 7 is a cross-sectional view of the implant shown in FIG. 6, during another step of constructing the implant;

FIG. 8 is a cross-sectional view of the implant shown in FIGS. 6 and 7 during another step for constructing the implant;

FIG. 9 is a cross-sectional view of the implant shown in FIGS. 6 - 8 and including an optional cuff;

FIG. 10 is a cross-sectional view of another embodiment of an implant shown during one step for constructing the implant;

FIG. 11 is a cross-sectional view of the implant shown in FIG. 10, during another step for constructing the implant; and

FIG. 12 is a cross-sectional view of the implant shown in FIGS. 10 and 11 in a final step for constructing the implant.

Detailed Description

With initial reference to FIG. 1, an implant is shown generally at 10. The implant 10 includes a composite of a hollow, rigid conduit 12. The conduit 12 includes a wall 14 defining an outer surface 16 and a hollow interior 18. In preferred embodiments, the wall 14 has a circular cross-section, forming a tube or cylinder 20. The conduit 12 includes a first portion 24, preferably corresponding to a vessel or vasculature portion, and a second portion 26, generally corresponding to a myocardial portion. The conduit 12 includes an open first end 28 that is defined by the vascular portion 24. The conduit 12 also includes an open second end 30 that is defined by the myocardial portion 26.

In FIG. 1, a cross-section of the myocardium 32 of a human heart is shown. As can be seen in FIG. 1, in preferred embodiments, the first portion 24 is dimensioned to be received within a lumen 34 of a coronary vasculature 36. As used herein, the term "vasculature" refers to veins or arteries. Note that the vasculature 36 resides exterior of the myocardium 32. The second portion 26 is dimensioned to extend from the vasculature 36 through the myocardium 32 and into a heart chamber 38. In preferred implementations, the heart chamber 38 will be the left ventricle 40. As can be seen in FIG. 1, the conduit 12 defines a blood flow pathway 42 within the interior 18

between the open first end 28 and the open second end 30. This allows for the flow of oxygenated blood directly from the left ventricle 40 through the pathway 42 and into the vasculature 36.

Turning now to FIG. 4, the implant 10 is illustrated enlarged and in cross-section. The implant 10 is shown as it would appear before being operably inserted in the environment shown in FIG. 1. In reference now to FIG. 2, in preferred embodiments, the implant 10 includes a scaffold 50 to provide framework or support overall to the implant 10. The scaffold 50 is generally made from a material that will provide strength and integrity to the overall implant 10 and with which will be able to withstand the muscular pressure exerted by systolic and diastolic contractions of the myocardium 32. The scaffold 50 may either be impermeable or permeable. Suitable materials for the scaffold 50 include titanium or stainless steel. If the scaffold 50 is designed to be permeable, the scaffold 50 is formed into a matrix such as a permeable mesh.

In the embodiment shown in FIG. 2, the scaffold 50 defines an interior volume 52, a first end 54 and an opposite, second end 56. The scaffold 50 also defines an exterior surface 58 and an opposite, interior surface 60. As can be seen in FIG. 2, the interior surface 60 is immediately adjacent to and lines the interior volume 52. In the particular embodiment shown in FIG. 2, the scaffold 50 is non-straight. In particular, the scaffold 50 defines an interior angle between a first portion 62 and a second portion 64. In the embodiment shown, the angle between the first portion 62 and the second portion 64 is between 80° - 100°, inclusive, preferably 90°. As such, the scaffold 50 is L-shaped.

In reference now to FIG. 3, the scaffold 50 is shown with a tubing 70 in covering relation to the scaffold 50. As can be seen in FIG. 3, the scaffold interior surface 60 is completely covered by the tubing 70 from the scaffold first end 54 all the way to the scaffold second end 56. Together, the scaffold interior surface 60 and the tubing 70 define a lumen 72. The lumen 72 corresponds to the interior 18 of the finished implant 10. The lumen 72 also forms at least a part of the blood pathway 42 (FIG. 1).

Still in reference to FIG. 3, the scaffold exterior surface 58 is also completely covered by the tubing 70 from the scaffold first end 54 to the scaffold second end 56. In this context, by "completely covered", it is meant that the tubing 70 is continuous and without apertures, openings, passages, slits, slots, or other voids such that

it forms a complete blanket over the scaffold 50 protecting the scaffold 50 from any exposures. From a review of FIG. 3, it can be seen that the tubing 70 completely encases the scaffold 50 to provide protection, durability, strength, and vascular compatibility to the scaffold 50. In preferred embodiments, the tubing 70 is made from expanded polytetrafluoroethylene (ePTFE).

FIGS. 2 - 4 illustrate example steps that may be followed to construct the implant 10. In FIG. 2, the tubing 70 is shown extended through the interior volume 52 of the scaffold 50. One way of accomplishing this step is by providing the scaffold 50 and inserting the tubing 70 through the interior volume 52 of the scaffold 50.

In general, the tubing 70 includes a wall 74 having a circular cross-section, such that the tubing 70 is generally cylindrical in shape. The tubing 70 includes an open first end 76, and an opposite, open second end 78. As can be seen in FIG. 2, the tubing 70 can be divided into three sections: a first section 80, a second section 82, and a third section 84. The first section 80 is a portion of the tubing that, during this step of the construction process in FIG. 2, extends from the first end 54 of the scaffold 50 exterior of the scaffold 50 in this step (but it is in subsequent steps, FIG. 3). That is, the first section 80 is not in contact with the scaffold 50. The second section 82 extends between the first section 80 and the third section 84. The second section 82 is the portion of the tubing 70 that is adjacent to and in contact with the scaffold 50 between the first end 54 and the second end 56. In the construction step shown in FIG. 2, the second section 82 extends along the interior surface 60 of the scaffold 50. The third section 84 projects from the second end 56 of the scaffold 50. The third section 84 is not in contact with the scaffold 50. The third section 84 defines the open second end 78, while the first section 80 defines the first open end 76.

FIG. 3 shows another step for constructing the implant 10. In FIG. 3, the tubing 70 can be seen to include at least a first fold 86 covering the scaffold first end 54. This may be accomplished by folding the first section 80 of the tubing 70 back against itself around the first end 54 and to cover the exterior surface 58 of the scaffold 50. In the particular embodiment shown, the first end 76 of the tubing 70 is adjacent to and against the scaffold second end 56. As can be seen in FIG. 3, the third section 84 remains

in the same form that it was in FIG. 2, that is, extending from the scaffold second end 56, with the tubing second end 78 being remote from the scaffold 50.

Next, the tubing 70 and the scaffold 50 are bonded together to form a composite 90. The bonding may be done in a variety of methods including mechanical bonding, chemical bonding, and thermal bonding. FIG. 4 illustrates the resulting implant 10 after the tubing 70 and the scaffold 50 have been bonded together. The resulting implant 10 in FIG. 4 is the same implant shown in FIG. 1.

Reference is now made to FIGS. 5 - 9. FIG. 5 illustrates another embodiment of an implant 100. The implant 100 is shown within a blood vessel 102. The blood vessel 102 can be a coronary vessel or any of the vessels in the lumen body. The implant 100 can be used to extend through the myocardium of a human heart, as described above in connection with the embodiment of FIG. 1. The implant 100 functions as a stent 103 to help insure the passage of blood through a pathway 104. In the one shown in FIG. 5, the implant 100 is cylindrical in shape having a wall 106, opposite first and second ends 108, 110, and an interior volume 112. The interior volume 112 forms a portion of the blood pathway 104.

FIGS. 6 - 8 show steps in constructing the implant 100. As with the embodiment of FIGS. 1 - 4, the implant 100 includes a scaffold 114 and tubing 116. The scaffold 114, in this embodiment, is straight and unbent. The scaffold 114 defines first and second opposite ends 118, 120, an exterior surface 122, and an opposite interior surface 124.

Still in reference to FIG. 6, the tubing 116 has an open first end 126 and an opposite second end 128. The tubing 116 can be divided into first, second, and third sections 131, 132, and 133, respectively. The first section 131 extends from the first end 118 of the scaffold 114 and is not in immediate contact with the scaffold 114 in FIG. 6. The second section 132 is the portion of the tubing 116 that is in contact with the scaffold 114. The second section 132 extends between the first and second ends 118, 120 and lines the interior surface 124 of the scaffold 114. The third section 133 extends from the scaffold 114 from the second end 120 and does not immediately contact the scaffold 114 in the FIG. 6 illustration.

FIG. 7 illustrates a second step in forming the implant 100. In FIG. 7, the implant 100 is shown after the first section 131 has been folded around the first end 118 of the scaffold 114 to form a first fold 136 in the tubing 116. Also shown in FIG. 7, the third section 133 has been folded around the second end 120 of the scaffold 114 to form a second fold 138 in the tubing 116. As can be appreciated by reviewing FIG. 7, the tubing 116 is folded back around each of the ends 118, 120 such that the tubing 116 completely encases the scaffold 114. That is, the first section 131 is folded around the first end 118 to cover the exterior surface 122, as the third section 133 is folded around the second end 120 to also cover the exterior surface 122. The first end 126 of the tubing 116 meets up with the second end 128 of the tubing 116 in a manner in which the ends 126, 128 either abut each other or overlap to form a seam or joint 140. The joint 140 can be along any portion of the scaffold 114. In the particular embodiment shown in FIG. 7, the joint 140 is at about the mid point between the first and second ends 118, 120 of the scaffold 114.

FIG. 8 illustrates the implant 100 after the tubing 116 and scaffold 114 are bonded to form bonded structure 142. As with the implant 10, the implant 100 may be formed by one or combinations of mechanical bonding, chemical bonding, and thermal bonding.

The implant 100 can include an optional sleeve or cuff 144 around the joint 140 containing a tissue integration material, such as tissue growth inducing substances. This is described in commonly assigned U.S. Patent No. 5,984,956, which is incorporated by reference herein.

Attention is next directed to the embodiment of FIGS. 10 - 12. An implant 150 is shown in FIG. 12, with steps in constructing the implant 150 shown in FIGS. 10 and 11. The implant 150 is analogous to the implant 10 of FIGS. 1 - 4 with the exception that the implant 150 is straight and unbent. The implant 150 is not L-shaped as the implant 10.

Other than the lack of an angle, the implant 150 is the same as the implant 10. As such, the implant 150 includes a scaffold 152 and tubing 154. The tubing 154 is bent around a first end 156 of the scaffold 152 to form a fold 158 adjacent to and against the first end 156. The tubing 154 is folded over the scaffold 152 such that the first end 160 of the tubing 154 is adjacent to and against the second end 162 of the scaffold 152.

In this manner, the tubing 154 completely encases the scaffold 152 by completely lining the interior surface 164 of the scaffold 152 and covering the exterior surface 166 of the scaffold 152. A second section 168 of the tubing 154 remains extending from the second end 162 and is out of immediate and adjacent contact with the scaffold 152. FIG. 12 shows the implant 150 after the scaffold 152 and tubing 154 are bonded to form a bonded implant structure 170. Again, the bonding can be done by one of, or combinations of, mechanical, chemical, and thermal bonding.

From a review of each of the embodiments in FIGS. 1 - 12, it should be appreciated that the implants formed have scaffolds that are completely encased and covered by tubing. In preferred embodiments, there is no portion of the scaffold wall (including interior surface, exterior surface, and end rims) that is left exposed -- all of these portions are covered by the tubing.

The implants 10, 100, and 150 can be used to treat human patients. In one application, the implant can be used in a method for performing a coronary vessel bypass procedure. This method includes forming a blood flow path, such as pathway 42 from heart chamber 38 directly to the coronary vessel 36 at a site in the vessel positioned between an obstruction in the vessel and tissue of the heart to be supplied with blood by the vessel. This step includes placing the implant 10, 100, 150 in the heart wall 32 between the chamber 38 and the vessel 36 with one end of the implant 10, 100, 150 protruding into the chamber 38 beyond an interior surface of the heart wall 32. The method includes the implant having tubing completely lining an interior surface and completely lining an exterior surface between opposite ends of the implant.

Methods for treating human patients also may include forming a blood path in a blood vessel by positioning an implant in the vessel. The implant would include implants of the type described herein.

The above description represents a complete description of example embodiments incorporating principles of the inventions. Many embodiments can be made.